SEP 2 8 2005

510(k) Summary

SUBMITTER:	DePuy Spine, Inc. 325 Paramount Drive Raynham, MA 02780
CONTACT PERSON:	Liz Lavelle
DATE PREPARED:	August 4, 2005
CLASSIFICATION NAME:	Appliance, Fixation, Spinal Interlaminal Orthosis, Spinal Pedicle Fixation
PROPRIETARY NAME:	EXPEDIUM™ Spine System 5.5mm Commercially Pure Titanium Spinal Rods
PREDICATE DEVICES:	EXPEDIUM™ Spine System (Merlin Spine System) - K033901 MOSS MIAMI™ Spinal System - K955348 MONARCH™ Spine System - K024348, K021148
DEVICE DESCRIPTION:	The EXPEDIUM™ Spine System Commercially Pure Titanium Spinal Rods are 5.5mm diameter rods available in various lengths. The rods are designed for use with previously cleared titanium alloy components of the EXPEDIUM™ Spine System, MOSS MIAMI™ Spinal System, and MONARCH™ Spine System which can accept a 5.5mm spinal rod, including monoaxial and polyaxial screws, hooks, and connectors. The rods will be labeled as components of the EXPEDIUM™ Spine System.
INTENDED USE:	**The EXPEDIUM™ Spine System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.**
MATERIALS:	Manufactured from Grade 3 commercially pure titanium conforming to ASTM F-67.
PERFORMANCE DATA:	Biomechanical test data were submitted to characterize the EXPEDIUM™ Spine System 5.5mm Commercially Pure Titanium Spinal Rod.

510(k) Summary

IX. 510(k) Summary

SUBMITTER:	DePuy Spine, Inc. 325 Paramount Drive Raynham, MA 02780
CONTACT PERSON:	Liz Lavelle
DATE PREPARED:	August 4, 2005
CLASSIFICATION NAME:	Appliance, Fixation, Spinal Interlaminal Orthosis, Spinal Pedicle Fixation
PROPRIETARY NAME:	5.5mm Commercially Pure Titanium Spinal Rods
PREDICATE DEVICES:	EXPEDIUM™ Spine System (Merlin Spine System) - K033901 MOSS MIAMI™ Spinal System - K955348 MONARCH™ Spine System - K024348, K021148
DEVICE DESCRIPTION:	The Commercially Pure Titanium Rods are 5.5mm diameter spinal rods available in various lengths. The rods are designed for use with previously cleared titanium alloy components of the MOSS MIAMI™ Spinal System which can accept a 5.5mm spinal rod, including screws, hooks, and connectors.
INTENDED USE:	The MOSS MIAMI™ Spine System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The MOSS MIAMI™ Spine Systems is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The MOSS MIAMI™ Spine System is also a hook and sacral/iliac screw fixation system of the noncervical spine indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis).

The EXPEDIUM™ Spine System 5.5mm Commercially Pure Titanium Rods may be used with mating titanium alloy components of the MOSS MIAMI™ Spine System which can accept a 5.5 mm diameter rod.

MATERIALS: Manufactured from Grade 3 commercially pure titanium conforming to ASTM F-67.

PERFORMANCE DATA: Biomechanical test data were submitted to characterize the 5.5mm Commercially Pure Titanium Spinal Rods.

510(k) Summary

SUBMITTER:	DePuy Spine, Inc. 325 Paramount Drive Raynham, MA 02780
CONTACT PERSON:	Liz Lavelle
DATE PREPARED:	August 4, 2005
CLASSIFICATION NAME:	Appliance, Fixation, Spinal Interlaminal Orthosis, Spinal Pedicle Fixation
PROPRIETARY NAME:	5.5mm Commercially Pure Titanium Spinal Rods
PREDICATE DEVICES:	EXPEDIUM™ Spine System (Merlin Spine System) - K033901 MOSS MIAMI™ Spinal System - K955348 MONARCH™ Spine System - K024348, K021148
DEVICE DESCRIPTION:	The Commercially Pure Titanium Rods are 5.5mm diameter spinal rods available in various lengths. The rods are designed for use with previously cleared titanium alloy components of the MONARCH ™ Spinal System which can accept a 5.5mm spinal rod, including screws, hooks, and connectors.
INTENDED USE:	The MONARCH™ Spine System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The MONARCH™ Spine System is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The MONARCH™ Spine System is also a hook and sacral/iliac screw fixation system of the noncervical spine indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis).

The MONARCH™ Spine System when used with pedicle screws are indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies). Levels of fixation are for the thoracic, lumbar and sacral spine.

The MONARCH™ Spine System Dual Rod Connectors can be used to connect MONARCH™ Spine System Rods to rods of other DePuy Spine 4.75mm, 5.5mm, and 6.35mm diameter rod systems.

The EXPEDIUM™ Spine System 5.5mm Commercially Pure Titanium Rods may be used with mating titanium alloy components of the MONARCH™ Spine System which can accept a 5.5 mm diameter rod.

MATERIALS: Manufactured from Grade 3 commercially pure titanium conforming to ASTM F-67.

PERFORMANCE DATA: Biomechanical test data were submitted to characterize the 5.5mm Commercially Pure Titanium Spinal Rods.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 8 2005

Ms. Liz Lavelle
Senior Regulatory Affairs Associate
Depuy Spine
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K052131
Trade Name: Expedium™ Spine System, Moss Miami™ Spine System and Monarch™ Spine System (Addition of 5.5 CP Ti Rods)
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: III
Product Code: NKB, MNI, MNH, KWP, KWQ
Dated: September 2, 2005
Received: September 6, 2005

Dear Ms. Lavelle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosures

III. Indications for Use

510(k) Number (if known): K052131

Device Name: EXPEDIUM™ Spine System 5.5mm Commercially Pure Titanium Rods

Indications For Use:

The EXPEDIUM™ Spine System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K052131

III. Indications for Use

510(k) Number (if known): K052131

Device Name: 5.5mm Commercially Pure Titanium Rods to MONARCH™ Spine System

Indications For Use:

The MONARCH™ Spine System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The MONARCH™ Spine System is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The MONARCH™ Spine System is also a hook and sacral/iliac screw fixation system of the noncervical spine indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis).

The MONARCH™ Spine System when used with pedicle screws are indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies). Levels of fixation are for the thoracic, lumbar and sacral spine.

The MONARCH™ Spine System Dual Rod Connectors can be used to connect MONARCH Spine System Rods to rods of other DePuy Spine 4.75mm, 5.5mm, and 6.35mm diameter rod systems.

The EXPEDIUM™ Spine System 5.5mm Commercially Pure Titanium Rods may be used with mating titanium alloy components of the MONARCH™ Spine System which can accept a 5.5 mm diameter rod.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K052131

III. Indications for Use

510(k) Number (if known): K052131

Device Name: 5.5mm Commercially Pure Titanium Rods to MOSS MIAMI™ Spine System

Indications For Use:

The MOSS MIAMI™ Spine System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The MOSS MIAMI™ Spine Systems is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The MOSS MIAMI™ Spine System is also a hook and sacral/iliac screw fixation system of the noncervical spine indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis).

The EXPEDIUM™ Spine System 5.5mm Commercially Pure Titanium Rods may be used with mating titanium alloy components of the MOSS MIAMI™ Spine System which can accept a 5.5 mm diameter rod.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N. Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052131